

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
25 January 2001 (25.01.2001)

PCT

(10) International Publication Number
WO 01/05352 A1(51) International Patent Classification⁷: A61J 7/00, 1/03, A61K 9/70(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, ER, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SL, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(21) International Application Number: PCT/GB00/02758

(22) International Filing Date: 18 July 2000 (18.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9916773.6 19 July 1999 (19.07.1999) GB
0002342.4 2 February 2000 (02.02.2000) GB(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(71) Applicants and

Published:

(72) Inventors: ASHWORTH, Andrew, John [GB/GB]; 22 Springfield, South Queensferry, West Lothian EH30 9XD (GB). ASHWORTH, Lorna, E., B. [GB/GB]; 22 Springfield, South Queensferry, West Lothian EH30 9XD (GB).

- *With international search report.*
- *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

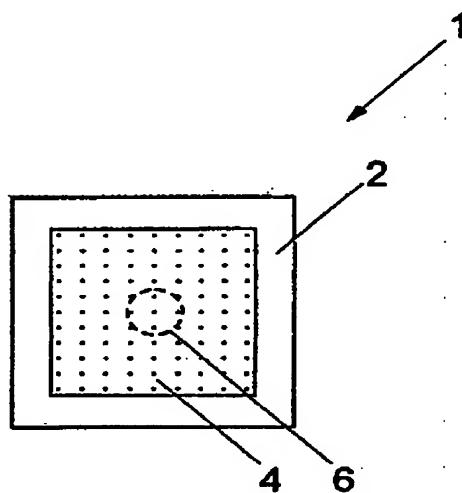
(74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G4 8QA (GB).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR ADMINISTRATION OF MEDICATION



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(57) Abstract: Apparatus and method for the mucosal administration of medication. The apparatus has a vehicle adapted for delivery of said medication. The vehicle is retrievable after use to allow a supervisor to ensure that the medication has been correctly administered and to prevent misuse of any unadministered drug. Typically the vehicle is adapted to be retrievable substantially intact after delivery.

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10 **Apparatus and Method for Administration of Medication**

11

12 This invention relates to an apparatus and method for
13 administration of medication.

14

15 Opiate/opioid addicts may be treated by controlled
16 administration of substitute medication. Some such
17 substitute medication is normally administered by
18 mucosal route under supervision. However such
19 medication has more potent effect if injected or
20 "snorted". There is also a thriving black market for
21 such medication. It is relatively simple for a patient
22 to divert such medication for alternative use or
23 resale, even when it is administered under supervision.

24

25 According to the present invention there is provided an
26 apparatus for the mucosal administration of medication
27 comprising a vehicle adapted for delivery of said
28 medication.

29

30 Said vehicle may be retrievable after use. Typically
31 said vehicle is adapted to be retrievable substantially
32 intact after delivery.

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2 Preferably said vehicle is adapted to enclose said
3 medication. Additionally or alternatively said vehicle
4 may be adapted to be impregnated with said medication.

5

6 Said vehicle may be adapted to fit in the mouth. Said
7 vehicle may be adapted to fit under the tongue.

8

9 Preferably said vehicle is comprised of material inert
10 to saliva. More preferably said vehicle is comprised
11 of material permeable to saliva.

12

13 Typically said vehicle comprises a permeable container.

14

15 Preferably said container is adapted to receive
16 medication during its manufacture.

17

18 Said container is preferably adapted to accommodate
19 medication in solid form. Said solid form may comprise
20 a tablet. Said solid form may comprise a frozen
21 liquid.

22

23 Preferably said container is sealed. Alternatively
24 said container is adapted to be sealed.

25

26 Further according to the present invention there is
27 provided a method of administration of medication
28 comprising the steps of:

29 including said medication in a vehicle;

30 supervising a patient while the vehicle is placed in a
31 patient's mouth;

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3

1 waiting until the contents of the vehicle have been
2 absorbed into the patient's bloodstream;
3 reclaiming the vehicle; and
4 ensuring the vehicle is intact.

5

6 Preferably said method comprises the step of sealing
7 said medication within a permeable container. More
8 preferably said method comprises the step of sealing
9 said medication within a permeable container during
10 manufacture of said container.

11

12 Embodiments of the present invention will now be
13 described by way of example only with reference to the
14 accompanying drawings in which:

15

16 Fig 1 is a permeable container in accordance with an
17 aspect of the invention; and

18

19 Fig 2 is a permeable container in accordance with a
20 further aspect of the invention.

21

22 Referring to the drawings, an apparatus for the mucosal
23 administration of medicament comprises a vehicle 1 in
24 the form of a container 2, 3 substantially of permeable
25 material. The container 2, 3 is manufactured of
26 material that is permeable to saliva, and that does not
27 react with saliva.

28

29 In the embodiment illustrated in Fig 1, the container 2
30 comprises a sealed pouch 4 of permeable material.
31 Medication 6 is placed within the pouch 4 during
32 manufacture of this container 2, and the pouch 4 is

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1 then sealed. The medication is thus contained within
2 the sealed pouch.
3
4 In the embodiment illustrated in Fig 2, the container 3
5 comprises a pouch 8 with an opening 10, wherein the
6 opening 10 is adapted to be sealed. The opening 10
7 permits inclusion of a medicament. In this embodiment
8 the pouch 8 is substantially of material that contains
9 a percentage of nylon. The edges of the opening 10 of
10 the pouch can be fused by heat sealing once a
11 medicament is placed therein.
12
13 Each vehicle 1 comprises a unique identifier to prevent
14 its substitution.
15
16 This vehicle 1 is useful in administration of
17 opiate/opiod medication to patients.
18
19 An example of appropriate patients would be recovering
20 drug addicts. There is always the temptation for such
21 patients to attempt to divert the medication for later
22 more potent use or resale. For this reason, the
23 medication is administered under supervision.
24
25 The medication is normally in tablet form and adapted
26 to be delivered by mucosal route. That is, the
27 medicament is designed to be absorbed under the tongue
28 or elsewhere within the mouth. Tablets used for this
29 purpose are small and easily hidden.
30
31 The administrator presents tablets to the patient in
32 the sealed container 2,3 of the invention, which he

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1 then retrieves - still sealed - when empty. This
2 allows the administrator to be satisfied that the
3 contents of the container 2,3 have been absorbed into
4 the bloodstream of the patient, and not diverted for
5 other purposes.

6

7 That is, since the vehicle 1 is recoverable intact,
8 there is a great degree of confidence that the
9 medication has been properly administered to the
10 intended patient.

11

12 The vehicle 1 of the instant invention also allows
13 administrators of medication to reduce the possibility
14 of diversion of medication with black market resale
15 value if it becomes a requirement that a repeat
16 prescription is only available on return of intact
17 containers 2,3. This will reduce the likelihood of
18 diversion of such medication for sale, for example by
19 pensioners.

20

21 In a further embodiment the structure of the vehicle 1
22 is impregnated with the medicament; or impregnated with
23 or made from material that reacts with medication
24 accommodated in the container 2,3 on dispensing.

25

26 The vehicle 1 also has application in administration of
27 drugs to unconscious or disabled patients. The size,
28 shape or nature of the vehicle 1 is adapted to prevent
29 inadvertent inhalation or swallowing of the vehicle 1.

30

31 For this purpose, the vehicle 1 has a portion adapted
32 to protrude from the mouth when it is in position. The

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1 protruding portion operates as a handle, allowing an
2 administrator to retain control of the vehicle 1, and
3 allowing easy removal of the spent vehicle 1 from a
4 patient's mouth. In one embodiment, the protruding
5 portion is a string or cord.

7 Details concerning the contents of the vehicle 1, for
8 example the dosage or patient's name or a serial number
9 or date, can be printed and displayed or otherwise
10 included on the surface of the material that comprises
11 the vehicle 1.

12
13 The vehicle 1 can be impregnated with, or otherwise
14 contain a pH indicator. That is, the vehicle 1 can be
15 customised for specific purposes.

17 The container 2, 3 will accommodate medication in
18 tablet form, or in any solid form such as a frozen
19 liquid.

21 In the embodiments of Figure 1 and Figure 2, the
22 container 2,3 is soft and porous, and resembles a
23 teabag. The material from which teabags are
24 manufactured is ideal for this vehicle 1. In use,
25 medication 6 in tablet form is enclosed within this
26 container 2,3. The medication 6 is either sealed in
27 the container 2 during its manufacture, or the
28 container 3 is filled and sealed by or on behalf of the
29 administrator. Each vehicle 1 contains a unique
30 identifier, such as a serial number.
31 The sealed container 2,3 is dispensed to the patient.
32 The patient is observed while he places the container

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1 2,3 in his mouth or under his tongue, for the period
2 during which the medication is dissolving and being
3 absorbed, and as he removes the empty container 2,3
4 from his mouth.

5

6 The administrator can then use the unique identifier to
7 satisfy himself that there has been no replacement of
8 containers 2,3 during this process. If this is the
9 case, the administrator can then examine the container
10 2,3 to satisfy himself that the container 2,3 has not
11 been tampered with, and remains intact.

12

13 The container 2,3 can also be made of material that is
14 designed to dissolve, but at a rate slower than that of
15 the medication it is adapted to contain. The surface
16 of the vehicle 1 can be impregnated with medication.

17

18 In one embodiment, the vehicle 1 comprises a piece of
19 material impregnated with a medicament. This
20 embodiment of the vehicle 1 does not require to be
21 sealed, but is still retrievable intact by the
22 administrator.

23

24 A further embodiment of the vehicle 1 comprises a
25 container 2,3 the surface of which can be impregnated
26 with material that changes the properties of the
27 medication contained in the container 2,3 on
28 dispensing.

29

30 The vehicle 1 can be used to administer medication to
31 unconscious patients, and to monitor its absorption.

32

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1 The vehicle 1 has application in administering
2 medication to patients who require supervision to
3 ensure that the medication is taken, such as geriatric
4 and paediatric patients. The vehicle 1 can be
5 coloured, flavoured, patterned or otherwise decorated
6 to make more palatable to children.

7

8 The vehicle 1 has further application for veterinary
9 use.

10

11 The common features of all embodiments of the vehicle 1
12 are that they remain intact throughout the procedure of
13 administration of medication, and are retrievable for
14 scrutiny after administration to confirm that
15 medication has been appropriately administered.

16

17 Improvements and modifications can be made to the above
18 without departing from the scope of the invention.

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1 CLAIMS

2

3 1. Apparatus for mucosal administration of medication
4 comprising a vehicle adapted for delivery of said
5 medication.

6

7 2. Apparatus as claimed in claim 1, wherein said
8 vehicle is retrievable after delivery.

9

10 3. Apparatus as claimed in either preceding claim,
11 wherein said vehicle is adapted to be retrievable
12 substantially intact after delivery.

13

14 4. Apparatus as claimed in any preceding claim,
15 wherein said vehicle is adapted to enclose said
16 medication.

17

18 5. Apparatus as claimed in any preceding claim,
19 wherein said vehicle is adapted to be impregnated
20 with said medication.

21

22 6. Apparatus as claimed in any preceding claim,
23 wherein said vehicle is adapted to fit in the
24 mouth.

25

26 7. Apparatus as claimed in any preceding claim,
27 wherein said vehicle is adapted to fit under the
28 tongue.

29

30 8. Apparatus as claimed in any preceding claim,
31 wherein said vehicle is comprised of material
32 inert to saliva.

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2 9. Apparatus as claimed in any preceding claim,
3 wherein said vehicle is comprised of material
4 permeable to saliva.

5

6 10. Apparatus as claimed in any preceding claim,
7 wherein said vehicle comprises a permeable
8 container.

9

10 11. Apparatus as claimed in Claim 10, wherein said
11 container is sealed.

12

13 12. Apparatus as claimed in Claim 10, wherein said
14 container is adapted to be sealed.

15

16 13. Apparatus as claimed in any preceding claim,
17 wherein said container is adapted to receive
18 medication during its manufacture.

19

20 14. Apparatus as claimed in any preceding claim,
21 wherein said container is adapted to accommodate
22 medication in solid form.

23

24 15. Apparatus as claimed in Claim 14, wherein said
25 solid form comprises a tablet or said solid form
26 comprises a frozen liquid.

27

28 16. Method for administration of medication comprising
29 the steps of:
30 including said medication in a vehicle;
31 supervising a patient while the vehicle is placed
32 in a patient's mouth;

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11

1 waiting until the contents of the vehicle have
2 been absorbed into the patient's bloodstream;
3 reclaiming the vehicle; and
4 ensuring the vehicle is intact.

5

6 17. Method as claimed in claim 16, wherein the method
7 further comprises the step of sealing said
8 medication within a permeable container.

9

10 18. Method as claimed in either of claims 16 or 17,
11 wherein the method further comprises the step of
12 sealing said medication within a permeable
13 container during manufacture of said container.

14

15 19. Apparatus for mucosal administration of medication
16 substantially as hereinbefore described with
17 reference to the accompanying drawings.

18

19 20. Method for administration of medication
20 substantially as hereinbefore described with
21 reference to the accompanying drawings.

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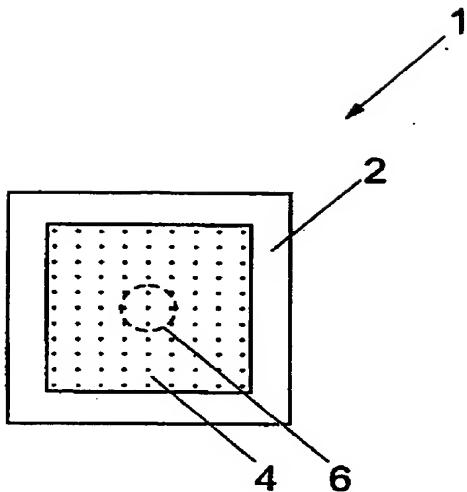


Fig. 1

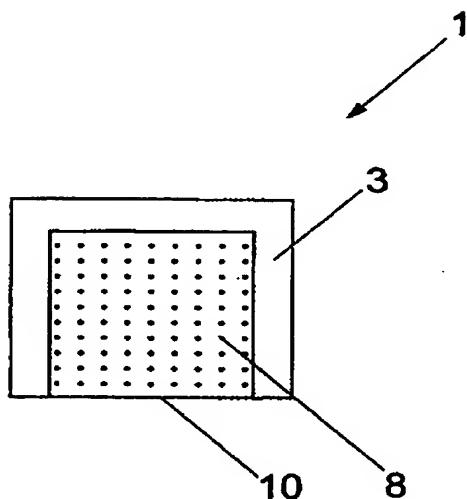


Fig. 2

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INTERNATIONAL SEARCH REPORT

Int'l. Appl. No.
PCT/GB 00/02758

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J7/00 A61J1/03 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 167 244 A (KJERSTAD RANDY E) 1 December 1992 (1992-12-01) column 5, line 14 – line 26 column 5, line 50 – line 57; figures	1-14, 17-20
X	WO 91 03271 A (UNIV UTAH RES FOUND) 21 March 1991 (1991-03-21) page 22, line 3 – line 11; figures 1-16	1-10, 14, 15, 19, 20
X	US 3 948 254 A (ZAFFARONI ALEJANDRO) 6 April 1976 (1976-04-06) column 4, line 41 – line 47 column 20, line 24 – line 38; figures 1-5	1-10, 14

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the International search

10 November 2000

Date of mailing of the International search report

16/11/2000

Name and mailing address of the ISA
European Patent Office, P.B. 5018 Patentstaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Canetz, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l. Appl. No.
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